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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/160,635 09/24/98 WONG

V A-60179-2/DJ

HM22/0410
FLEHR HOHBACH TEST ALBRITTON & HERBERT
STE 3400
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111

EXAMINER

WERNER, E

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/160635

Applicant(s)

Wong

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/19/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 10-33 is/are pending in the application.
- Of the above claim(s) 12, 14-17, 19-29, 32, 33 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 10, 11, 13, 18, 30, 31 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 10, 11, 13 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Bernstein et al.

3/22/03
Bernstein et al teaches soluble cationic release modifiers in matrices of biocompatible polymers (abstract, column 5 lines 27-35). Polylactide glycoside is disclosed (column 3, line 62). 20-30% modifier is disclosed (column 5 lines 10-12). Steroids are specified (column ⁴7 line 34).

Biodegradable polymers are specified (column 3 line 56). Microspheres are disclosed (column 12 line 8).

Applicants argue that Bernstein et al fail to disclose pairing the modulator to the hydrophobicity of the active. However, applicants claim A composition, not a method of making. The anticipatory composition discloses a steroid and soluble cationic release modifiers which meet the claimed hydrophobic active and hydrophilic modifier. As to the now claimed ocular implant, intended uses are not considered patentable limitations during patent prosecution.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Art Unit: 1617

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, 13, 18, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 311065 ('065).

'065 teaches granules comprising an active, a carrier, copolymer, and an additives (low MW) polylactic acid, or a pore-former, lactose (page 4 lines 10-12). Both (low MW) polylactic acid and lactose accelerate drug release (page 6 lines 55-56 and page 7 lines 10-11). Mid-range MW polylactide co-glycolide is disclosed as the carrier (page 2 lines 25-32).

No claims allowed.

The examiner notes that applicants elected the hydrophilic modulator (other than hydroxy propyl methyl cellulose) and a hydrophobic active in claim 11. Claim 12 remains non-elected, contrary to applicants assertion on the bottom of page 2, paper # 11 ("Response to Office Action mailed June 12, 2000"). See also the "Response to the restriction requirement" paper # 7 filed 2/22/00. The examiner further notes that now claimed retardants are disclosed as hydrophobic (page 5, line 18).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1617

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman:mv

March 12, 2001


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500